SUBCHAPTER A—GENERAL PROVISIONS

PART 400—INTRODUCTION; DEFINITIONS

Subpart A [Reserved]

Subpart B—Definitions

Sec.

Subpart C—OMB Control Numbers for Approved Collections of Information

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. Chapter 35.

Subpart A [Reserved]

Subpart B—Definitions

§ 400.200 General definitions.

In this chapter, unless the context indicates otherwise—

Act means the Social Security Act, and titles referred to are titles of that Act.

Administrator means the Administrator, Centers for Medicare & Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA).

ALJ stands for administrative law judge.

Area means the geographical area within the boundaries of a State, or a State or other jurisdiction, designated as constituting an area with respect to which a Professional Standards Review Organization or a Utilization and Quality Control Peer Review Organization has been or may be designated.

CMP stands for competitive medical plan.

Conditions of participation includes *requirements for participation* as the latter term is used in part 483 of this chapter.

Condition level deficiencies includes deficiencies with respect to ''level A requirements'' as the latter term is used in parts 442 and 483 of this chapter.

CORF stands for comprehensive outpatient rehabilitation facility.

CFR stands for Code of Federal Regulations.

CMS stands for Centers for Medicare & Medicaid Services, formerly the Health Care Financing Administration (HCFA).

CY stands for calendar year.

DAB stands for Departmental Appeals Board.

Department means the Department of Health and Human Services (HHS), formerly the Department of Health, Education, and Welfare.

ESRD stands for end-stage renal disease.

FDA stands for the Food and Drug Administration.

FQHC means Federally qualified health center.

FR stands for FEDERAL REGISTER.

FY stands for fiscal year.

HCPP stands for health care prepayment plan.

HHS stands for the Department of Health and Human Services.

HHA stands for home health agency.

HMO stands for health maintenance organization.

ICF stands for intermediate care facility.

ICF/MR stands for intermediate care facility for the mentally retarded.

Medicaid means medical assistance provided under a State plan approved under title XIX of the Act.

Medicare means the health insurance program for the aged and disabled under title XVIII of the Act.

NCD stands for national coverage determination.

OASDI stands for the Old Age, Survivors, and Disability Insurance program under title II of the Act.

OIG stands for the Department's Office of the Inspector General.

QDWI stands for Qualified Disabled and Working Individual.

QIO stands for quality improvement organization.

QMB stands for Qualified Medicare Beneficiary.

Qualified Disabled and Working Individual means an individual who—

(1) Is eligible to enroll for Medicare Part A under section 1818A of the Act.

(2) Has income, as determined in accordance with SSI methodologies, that does not exceed 200 percent of the Federal poverty guidelines (as defined and revised annually by the Office of Management and Budget) for a family of the size of the individual's family;

(3) Has resources, as determined in accordance with SSI methodologies, that do not exceed twice the relevant maximum amount established, for SSI eligibility, for an individual or for an individual and his or her spouse; and

(4) Is not otherwise eligible for Medicaid.

Qualified Medicare Beneficiary means an individual who—

(1) Is entitled to Medicare Part A, with or without payment of premiums, but is not entitled solely because he or she is eligible to enroll as a QDWI;

(2) Has resources, as determined in accordance with SSI methodologies, that do not exceed twice the maximum amount established for SSI eligibility; and

(3) Has income, as determined in accordance with SSI methodologies, that does not exceed 100 percent of the Federal poverty guidelines.

Quality improvement organization means an organization that has a contract with CMS, under part B of title XI of the Act, to perform utilization and quality control review of the health care furnished, or to be furnished, to Medicare beneficiaries.

Regional Administrator means a Regional Administrator of CMS.

Regional Office means one of the regional offices of CMS.

RHC stands for rural health clinic.

RRB stands for Railroad Retirement Board.

Secretary means the Secretary of Health and Human Services.

SNF stands for skilled nursing facility.

Social security benefits means monthly cash benefits payable under section 202 or 223 of the Act.

SSA stands for Social Security Administration.

United States means the fifty States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

U.S.C. stands for United States Code.

[48 FR 12534, Mar. 25, 1983, as amended at 49 FR 7206, Feb. 27, 1984; 50 FR 15326 and 15358, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985; 51 FR 43197, Dec. 1, 1986; 52 FR 27764, July 23, 1987; 56 FR 8852, Mar. 1, 1991; 56 FR 38077, Aug. 12, 1991; 57 FR 24975, June 12, 1992; 57 FR 55912, Nov. 25, 1992; 63 FR 35065, June 26, 1998; 63 FR 52611, Oct. 1, 1998; 63 FR 68690, Dec. 14, 1998; 66 FR 39452, July 31, 2001; 67 FR 36540, May 24, 2002]

§ 400.202 Definitions specific to Medicare.

As used in connection with the Medicare program, unless the context indicates otherwise—

Beneficiary means a person who is entitled to Medicare benefits.

Carrier means an entity that has a contract with CMS to determine and make Medicare payments for Part B benefits payable on a charge basis and to perform other related functions.

Critical access hospital (CAH) means a facility designated by HFCA as meeting the applicable requirements of section 1820 of the Act and of subpart F of part 485 of this chapter.

Departmental Appeals Board means: (1) Except as provided in paragraphs (2) and (3) of this definition, a Board established in the office of the Secretary, whose members act in panels to provide impartial review of disputed decisions made by operating components of the Department or by ALJs.

(2) For purposes of review of ALJ decisions under part 405, subparts G and H; part 417, subpart Q; part 422, subpart M; and part 478, subpart B of this chapter, the Medicare Appeals Council designated by the Board Chair.

(3) For purposes of part 426 of this chapter, a Member of the Board and, at the discretion of the Board Chair, any other Board staff appointed by the Board Chair to perform a review under that part.

Entitled means that an individual meets all the requirements for Medicare benefits.

Essential access community hospital (EACH) means a hospital designated by CMS as meeting the applicable requirements of section 1820 of the Act and of subpart G of part 412 of this chapter, as in effect on September 30, 1997.

GME stands for graduate medical education.

Hospital insurance benefits means payments on behalf of, and in rare circumstances directly to, an entitled individual for services that are covered under Part A of title XVIII of the Act.

Intermediary means an entity that has a contract with CMS to determine and make Medicare payments for Part A or Part B benefits payable on a cost basis and to perform other related functions.

Local coverage determination (LCD) means a decision by a fiscal intermediary or a carrier under Medicare Part A or Part B, as applicable, whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with section 1862(a)(1)(A) of the Act. An LCD may provide that a service is not reasonable and necessary for certain diagnoses and/or for certain diagnosis codes. An LCD does not include a determination of which procedure code, if any, is assigned to a service or a determination with respect to the amount of payment to be made for the service.

Medicare integrity program contractor means an entity that has a contract with CMS under section 1893 of the Act to perform exclusively one or more of the program integrity activities specified in that section.

Medicare Part A means the hospital insurance program authorized under Part A of title XVIII of the Act.

Medicare Part B means the supplementary medical insurance program authorized under Part B of title XVIII of the Act.

Medicare Part C means the choice of Medicare benefits through Medicare Advantage plans authorized under Part C of the title XVIII of the Act.

Medicare Part D means the voluntary prescription drug benefit program authorized under Part D of title XVIII of the Act.

National coverage determination (NCD) means a decision that CMS makes regarding whether to cover a particular service nationally under title XVIII of the Act. An NCD does not include a determination of what code, if any, is assigned to a service or a determination with respect to the amount of payment to be made for the service.

Nonparticipating supplier means a supplier that does not have an agreement with CMS to participate in Part B of Medicare in effect on the date of the service.

Participating supplier means a supplier that has an agreement with CMS to participate in Part B of Medicare in effect on the date of the service.

Payment on an assignment-related basis means payment for Part B services—

(1) To a physician or other supplier that accepts assignment from the beneficiary, in accordance with § 424.55 or § 424.56 of this chapter;

(2) To a physician or other supplier after the beneficiary's death, in accordance with § 424.64(c)(1) of this chapter; or

(3) To an entity that pays the physician or other supplier under a health benefit plan, in accordance with § 424.66 of this chapter.

Provider means a hospital, a CAH, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services.

Railroad retirement benefits means monthly benefits payable to individuals under the Railroad Retirement Act of 1974 (45 U.S.C. beginning at section 231).

Services means medical care or services and items, such as medical diagnosis and treatment, drugs and biologicals, supplies, appliances, and equipment, medical social services, and use of hospital, CAH, or SNF facilities.

Supplementary medical insurance benefits means payment to or on behalf of an entitled individual for services covered under Part B of title XVIII of the Act.

Supplier means a physician or other practitioner, or an entity other than a

provider, that furnishes health care services under Medicare.

[48 FR 12534, Mar. 25, 1983, as amended at 48 FR 56024, Dec. 16, 1983; 49 FR 3658, Jan. 30, 1984; 51 FR 43197, Dec. 1, 1986; 52 FR 27764, July 23, 1987; 55 FR 24567, June 18, 1990; 56 FR 8852, Mar. 1, 1991; 58 FR 30666, May 26, 1993; 59 FR 6576, Feb. 11, 1994; 60 FR 63175, Dec. 8, 1995; 62 FR 46025, Aug. 29, 1997; 62 FR 59098, Oct. 31, 1997; 63 FR 35065, June 26, 1998; 68 FR 63715, Nov. 11, 2003; 70 FR 4525, Jan. 28, 2005; 72 FR 48885, Aug. 24, 2007]

§ 400.203 Definitions specific to Medicaid.

As used in connection with the Medicaid program, unless the context indicates otherwise—

Applicant means an individual whose written application for Medicaid has been submitted to the agency determining Medicaid eligibility, but has not received final action. This includes an individual (who need not be alive at the time of application) whose application is submitted through a representative or a person acting responsibly for the individual.

Federal financial participation (FFP) means the Federal Government's share of a State's expenditures under the Medicaid program.

FMAP stands for the Federal medical assistance percentage, which is used to calculate the amount of Federal share of State expenditures for services.

Medicaid agency or *agency* means the single State agency administering or supervising the administration of a State Medicaid plan.

Nursing facility (NF), effective October 1, 1990, means an SNF or an ICF participating in the Medicaid program.

PCCM stands for primary care case manager.

PCP stands for primary care physician.

Provider means either of the following:

(1) For the fee-for-service program, any individual or entity furnishing Medicaid services under an agreement with the Medicaid agency.

(2) For the managed care program, any individual or entity that is engaged in the delivery of health care services and is legally authorized to do so by the State in which it delivers the services.

Recipient means an individual who has been determined eligible for Medicaid.

Services means the types of medical assistance specified in section 1905(a) of the Act and defined in subpart A of part 440 of this chapter.

State means the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa and the Northern Mariana Islands.

State plan or *the plan* means a comprehensive written commitment by a Medicaid agency, submitted under section 1902(a) of the Act, to administer or supervise the administration of a Medicaid program in accordance with Federal requirements.

[48 FR 12534, Mar. 25, 1983, as amended at 50 FR 33029, Aug. 16, 1985; 56 FR 8852, Mar. 1, 1991; 57 FR 29155, June 30, 1992; 67 FR 41094, June 14, 2002]

Subpart C—OMB Control Numbers for Approved Collections of Information

SOURCE: 49 FR 4477, Feb. 7, 1984, unless otherwise noted.

§ 400.300 Scope.

This subpart collects and displays control numbers assigned by the Office of Management and Budget (OMB) to collections of information contained in CMS regulations, in accordance with OMB's regulations for controlling paperwork burdens on the public, 5 CFR part 1320. CMS intends that the subpart comply with the requirements of section 3507(f) of the Paperwork Reduction Act of 1980, 44 U.S.C. chapter 35 which requires that agencies shall not engage in a ''collection of information'' without obtaining a control number from OMB.

§ 400.310 Display of currently valid OMB control numbers.

Sections in 42 CFR that contain collections of information	Current OMB control Nos.
403.510	0938—0641
405.509	0938—0666
405.512	0938—0008
405.2112, 405.2123, 405.2134, 405.2136–405.2140, 405.2171	0938—0386
409.43	0938—0365
410.105	0938—0267
411.25, 411.32	0938—0564

Sections in 42 CFR that contain collections of information	Current OMB control Nos.
411.54	0938—0558
411.165	0938—0564
411.404, 411.406	0938—0465
411.408	0938—0566
412.42	0938—0666
412.92	0938—0477
412.105	0938—0456
412.230, 412.232, 412.234, 412.236, 412.254, 412.260, 412.266, 412.278	0938—0573
415.60	0938—0301
415.162	0938—0301
416.43	0938—0506
416.47	0938—0266 and 0938—0506
417.126	0938—0472
417.436, 417.801	0938—0610
418.22, 418.24, 418.28, 418.56, 418.58, 418.70, 418.74	0938—0302
418.30, 418.82, 418.83, 418.96, 418.100	0938—0475
418.96, 418.100	0938—0302
421.117	0938—0542
424.3	0938—0008
424.5, 424.7, 424.20	0938—0454
424.22	0938—0489
424.32, 424.34	0938—0008
431.17	0938—0467
431.50, 431.52, 431.55	0938—0247
431.107	0938—0610
431.306	0938—0467
431.625	0938—0247
431.630	0938—0445
431.800	0938—0247
431.806, 431.830, 431.432, 431.834, 431.836	0938—0438
432.50	0938—0459
433.36, 433.37	0938—0247
433.68, 433.74	0938—0618
433.110, 433.112–433.114, 433.116, 433.117, 433.119–433.121, 433.123, 433.127, 433.130, 433.131, 433.135	0938—0247
433.138	0938—0502 0938—0553 and 0938—0555
433.139	0938—0459 0938—0554 and 0938—0555
434.27	0938—0572
434.28	0938—0610
435.1, 435.910, 435.919, 435.920, 435.940, 435.945, 435.948, 435.952, 435.953, 435.955, 435.960, 435.965, 435.1003, 441.11, 441.15, 441.20	0938—0247
441.56, 441.58, 441.60, 441.61	0938—0354
441.302	0938—0449
441.303	0938—0272 and 0938—0449
441.351, 441.352, 441.353, 441.356, 441.365	0938—0613
442.505	0938—0366
447.31	0938—0287
447.45, 447.50, 447.51, 447.52	0938—0247
447.53	0938—0429
447.55	0938—0247
447.253	0938—0366 0938—0523 and 0938—0556
447.255	0938—0193
447.272, 447.299	0938—0618
447.302, 447.331, 447.332, 447.333	0938—0247
456.80	0938—0247
456.654	0938—0445
456.700, 456.705, 456.709, 456.711, 456.712	0938—0659
462.102, 462.103	0938—0526
466.70, 466.72, 466.74	0938—0445
466.78	0938—0445 and 0938—0665
466.80, 466.94	0938—0445
473.18, 473.34, 473.36, 473.42	0938—0443
476.104, 476.105, 476.116, 476.134	0938—0426
481.61	0938—0328
482.12, 482.21, 482.22, 482.27, 482.30, 482.41, 482.43, 482.53, 482.56, 482.57, 482.60, 482.62	0938—0328
483.10	0938—0610
483.410, 483.420, 483.440, 483.460, 483.470	0938—0366
484.1, 484.2	0938—0365
484.10	0938—0365 and 0938—0610
484.12, 484.14, 484.16, 484.18, 484.30, 484.32, 484.34, 484.36, 484.48, 484.52	0938—0365
485.56, 485.58, 485.60, 485.64, 485.66	0938—0267 and 0938—0538
485.709, 485.711, 485.717, 485.719, 485.721, 487.723, 485.725, 485.727	0938—0336
486.104, 486.106, 486.110	0938—0338
486.155, 486.161, 486.163	0938—0336
488.10	0938—0646
488.18	0938—0667
488.26	0938—0646
489.20	0938—0564 and 0938—0667
489.24	0938—0334 0938—0663 and 0938—0667
489.102	0938—0610
491.9, 491.10	0938—0334
493.35, 493.37, 493.39, 493.43, 493.45, 493.47, 493.49, 493.51, 493.53,.	
493.55, 493.60, 493.61, 493.62, 493.63	0938—0612
493.614, 493.633, 494.634	0938—0607
493.801–493.1285, 493.1425, 493.1701, 493.1703, 493.1705, 493.1707, 493.1709, 493.1711, 493.1713, 493.1715, 493.1717, 493.1719, 493.1721, 493.1775, 493.1776, 493.1777, 493.1780, 493.2001	0938—0612
494.52, 494.54, 494.56, 494.58, 494.64	0938—0608
498.22, 498.40, 498.58, 498.82	0938—0508
1004.40, 1004.50, 1004.60, 1004.70	0938—0444

[60 FR 50445, Sept. 29, 1995, as amended at 60 FR 63188, Dec. 8, 1995]

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

Subpart A [Reserved]

Subpart B—Confidentiality and Disclosure

Sec.